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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,504	11/18/2005	Catherine Symonds	B0192.70059US00	4329

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
07/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,504	SYMONDS ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,11,14-16,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 10-11, 14-16, and 18-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner for the current application at the USPTO has changed. Examiner Jean-Louis can be reached at 571-270-3503.

Response to Amendment

This Office Action is in response to the amendment submitted on 04/25/08. Claims 1, 10-11, 14-16, and 18-19 are currently pending in the application, with claims 12-13 and 17 having being cancelled. Accordingly, claims 1, 10-11, 14-16, and 18-19 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's argument with respect to the 35 U.S.C. § 102 (b) rejection has been fully considered. In light of applicant's amendment, the rejection under 35 U.S.C. § 102 (b) is hereby withdrawn.

Applicant's contention that Maurer et al. does not teach treatment of patients with brachial plexus injury but rather cancer patients has been fully acknowledged but is not found persuasive. Maurer et al. teach the beneficial use of the cannabinoid, THC, in 2.5 mg, 5 mg and 10 mg range (i.e. a dose less than 37.5 and 25 mg) in the treatment of patients with pain due to spinal cord and central nervous pathology (see pg. 1, left col.

Introduction, paragraph 2; right col., paragraph 3, and Summary). In fact, Maurer et al. teach that their patient had defined symptoms due to an extended spinal cord lesion (see pg. 3, left col. Discussion section) which meets the definition of brachial plexus avulsion that applicant himself has provided in his/her rebuttal. Moreover, it is well delineated in the prior art that tumors and compression due to tumors may also lead to the symptoms of brachial plexus injury (see Selvaggi, pg. 460, right col.). Moreover, Maurer et al. teach that THC improved the quality of sleep in their patient (see pg. 2, right col. last paragraph). Thus, one of ordinary skill in the art in view of Berman and Maurer would have been motivated to administer cannabis extract (i.e. composed of THC and CBD) in the dosage taught by Maurer et al. for the treatment of pain associated with spinal cord lesions including that of brachial plexus avulsion with the reasonable expectation of providing a method efficacious in improving symptoms associated with spinal cord pathology.

Applicant's argument with respect to Maurer and Berman who do not teach the recited dose of THC as claimed by applicant has been fully considered but is not found persuasive. Maurer et al. clearly teach the use of low dose THC in the treatment of spinal cord pathology in a range of 2.5, 5, and 10 mg. While Berman did not explicitly teach the aforementioned dosages, Berman in view of Maurer et al. does suggest the use of low dose THC for beneficial effect for pain due to spinal cord lesions. For the foregoing reasons, the rejection of claims 11 and 15-18 under 35 U.S.C. § 103 (a) remains proper and is maintained.

However, In view of applicant's amendment and cancellation of claims 12-13 and 17, the following modified 103 (a) Final rejection is being made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 10-11, 14-16 and 18-19 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Berman et al. (Pain, 1988, Vol. 75,pgs. 199-207, previously submitted) as evidenced by Werner et al. (US 2004/0138293 A1) in view of Maurer et al. (Eur. Arch. Psychiat. Clin. Neurosci. 1990, pgs. 1-4, previously submitted).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Berman et al. teach the use of surgery and analgesics to alleviate the intractable neuropathic pain which is chronically-associated with injury of the brachial plexus which involves spinal cord root avulsion (Abstract; 1st¶ (lines 6-7); see p. 199). It is noted that some avulsion injuries also may involve spinal cord damage (1st¶ (line 5); see p. 199). Specifically, Berman et al. teach that 2 out of 3 patients using cannabis as an analgesic drug therapy had reported some benefit (see section entitled, "3.5 Analgesics," p. 203 and Table 8 on p. 207). It is well known in the prior art that both delta-9-THC (THC) and cannabidiol (THC) are active agents found in the drug, cannabis.

Berman et al., however, does not teach the use of cannabis for the treatment of sleep disturbance (claim 11) nor provide the specific ratios of THC and CBD, or packaging for delivery as sublingual or buccal spray.

Werner et al. has been provided to demonstrate that cannabis is well known in the art to be administered in a mixture ratio of 3:1 to 1:2 THC to CBD for peroral administration for neuropathic pain or pain associated with neurological disorders and known to contain both TCH and CBD as CBD enhances the pharmacological beneficial effects of the composition (see pg. 1, paragraph 002-0004, 0006, 0011; pg. 3, paragraph 0021, 0024).

Maurer et al. teach that delta-9-THC has a beneficial effect to improve sleep disturbances in a patient suffering from a spinal cord pathology which is associated with pain and spasticity (see p. 1, 2nd ¶). Importantly, Maurer et al. also teach that their patient had defined symptoms due to an extended spinal cord lesion (see pg. 3, left col. Discussion section). In this double blind study, a dose-finding trial was conducted using 2.5 mg, 5 mg and 10 mg THC administered per orally in the form of impregnated sugar lumps (see "Design of the Study", p. 2). Furthermore, Maurer et al. teach that THC treatment significantly reduced the frequency of awakening compared to placebo (see Table 2, p. 3). Likewise, THC treatment also significantly increased the duration of sleep compared to placebo (see Table 2, p. 3). In this study, pain, sleep and mood was found to be rated together with codeine as being superior to placebo (see "Discussion," 4th ¶; p.3). Maurer et al. teach that a purified component of THC may be per orally administered for the treatment of pain, sleep disturbance and spastic movements in a patient suffering from spinal cord damage due to an ependymoma.

Berman et al. taught analgesic benefit following administration of cannabis in 2 out of 3 patients suffering from pain which was associated with brachial plexus avulsion. This suggests that the effect of the cannabis was pharmacological and unlikely mediated by the surgical procedure itself. Both THC and CBD are well-known art-recognized active components of cannabis extract that can be made into specific ratios for improved pharmacological effects as taught by Werner et al. above. Because Berman et al. taught analgesic effects of cannabis administration and Maurer et al.

taught beneficial effects of THC administration, one of ordinary skill in the art at the time of the invention would have found it obvious to isolate extracts from cannabis or medicinal extracts of cannabis to treat pain due to spinal cord damage or brachial plexus injury.

Moreover, it would have been well within the purview of the skilled artisan to provide particular conventional oral formulations such as capsules, tablets, as well as buccal sprays in these patients as these are deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

07/25/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617